IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

KILEY WOLFE,	:	**CIVIL ACTION**
	:	
Plaintiff,	:	
	:	
v.	:	**NO. 07-348**
	:	
MCNEIL-PPC, INC.; MCNEIL CONSUMER & SPECIALTY PHARMACEUTICALS, a division of MCNEIL-PPC, INC.; MCNEIL CONSUMER HEALTHCARE, a division of MCNEIL PPC, INC.; JOHNSON & JOHNSON, INC.; and JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT, LLC,	:	
	:	
Defendants.	:	

DuBOIS, J. **March 30, 2011**

M E M O R A N D U M

I. INTRODUCTION

In this products liability action, plaintiff Kiley Wolfe alleges that the Children's Motrin manufactured and marketed by defendants caused her to develop serious, life-altering illnesses. Presently before the Court is defendants' motion for summary judgment. For the reasons that follow, that motion is denied as to plaintiff's failure-to-warn claims and claim for punitive damages and granted in all other respects.

II. BACKGROUND[1]

In May 1996, plaintiff was nine years old and lived with her family in Bath, Maine. During a trip to Louisiana over Memorial Day weekend that year, plaintiff complained to her mother, Janet Leland, that she had a headache. (Leland Dep. at 89:21-23.) Plaintiff was still ill when she arrived home in Maine the evening of Memorial Day, May 27. (Id. at 92:13-15.) Leland took plaintiff to her pediatrician, Dr. Mulla, two days later on Wednesday, May 29. (Defs.' and Pl.'s Statements of Undisputed Facts ("SUF") ¶ 6.)

Dr. Mulla recommended Leland give her daughter Children's Motrin to help relieve her symptoms, which by then included a headache, stomach pains and a fever. (Leland Dep. at 96:5-97:12.) Children's Motrin is an over-the-counter ("OTC") non-steroidal anti-inflammatory drug, generically referred to as ibuprofen. (SUF ¶ 33.) Plaintiff asserts that all of the defendants are involved in the design, testing, manufacturing, marketing and/or selling of Children's Motrin.

A. Plaintiff's Injuries

Despite taking Children's Motrin, plaintiff's symptoms did not improve. Instead, she developed a rash on her cheeks. (Leland Dep. at 105:8-19.) Nonetheless, nurses at plaintiff's pediatrician's office advised Leland to continue administering the drug to plaintiff. (Id. at 106:17-19.) Leland proceeded to give plaintiff doses of Children's Motrin until Saturday, June 1, when she noticed blisters on plaintiff's ears while the family was staying in Boston. (Id. at 108:13-22.)

Later that day, Leland took her daughter to Boston Children's Hospital. (Id. at 130:9-12.)

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[1] As required on a motion for summary judgment, the facts as set forth in this Memorandum are presented in the light most favorable to plaintiff, the non-moving party.

Doctors there diagnosed her with Stevens-Johnson Syndrome ("SJS") (See Pl.'s Resp. to Mot. for Summ. J., Exs. D-E.)[2] While hospitalized, plaintiff exhibited symptoms of acute Vanishing Bile Duct Syndrome ("VBDS"). (See id., Ex. C at 14:16-17.)[3] Because of damage to her liver, plaintiff eventually required a liver transplant. (See id., Ex. B at 745.)

B. The Warning Label

At the time of plaintiff's illness, the FDA-approved warning label on OTC Children's Motrin included, inter alia, warnings to "call your doctor" if:

- "Your child does not get any relief within first day (24 hours) of treatment, or pain or fever gets worse.";
- "Redness or swelling is present in the painful area.";
- "Sore throat is severe, lasts for more than 2 days or occurs with fever, headache, rash, nausea or vomiting."; or
- "Any new symptoms appear."

(SUF ¶ 38.)

In 2006, the FDA recommended that warnings for OTC ibuprofen products be strengthened. (Pl.'s Resp. to Mot. for Summ. J., Ex. F at 9.) Specifically, the FDA recommended that such labels include reference to skin reddening, rashes and blisters – allergic reactions associated with SJS – and warn customers that "[i]f an allergic reaction occurs, stop use and seek medical help right away." (Id.)

The first time Leland administered the drug to plaintiff, she did not read the warnings and

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[2] SJS is "a rare, serious disorder in which your skin and mucous membranes react severely to a medication or infection." Mayo Clinic, Stevens-Johnson Syndrome, http://www.mayoclinic.com/health/stevens-johnson-syndrome/DS00940 (last visited Mar. 23, 2011). The disease is "sometimes fatal." Dorland's Illustrated Medical Dictionary 1833 (30th ed. 2003).

[3] VBDS is a condition where the bile ducts in the liver are destroyed. (See Pl.'s Resp. to Defs.' Mot. for Summ. J., Ex. C at 14:20-21.)

only checked the dosage. (Leland Dep. at 101:3-4.) Later in the week, however, she did examine the box and bottle to "see if there was anything on there that I should look for." (Id. at 101:8-13.)

C. The Present Action

Plaintiff now resides in Louisiana. She initiated this action in 2007, alleging that Children's Motrin caused her to develop SJS and VBDS and that defendants were thus liable to her under a variety of legal theories. All defendants have moved jointly for summary judgment; that motion is fully briefed and ripe for review.

III. LEGAL STANDARD

In considering a motion for summary judgment, "the court is required to examine the evidence of record in the light most favorable to the party opposing summary judgment, and resolve all reasonable inferences in that party's favor." Wishkin v. Potter, 476 F.3d 180, 184 (3d Cir. 2007). The party opposing the motion, however, cannot "rely merely upon bare assertions, conclusory allegations or suspicions" to support its claim. Fireman's Ins. Co. v. DuFresne, 676 F.2d 965, 969 (3d Cir. 1982). After examining the evidence of record, a court should grant summary judgment if the moving party "shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); accord Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986).

A factual dispute is material when it "might affect the outcome of the suit under the governing law," and genuine when "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). "Where the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party, there is no 'genuine issue for trial.'" Matsushita Elec. Indus. Co. v. Zenith

Radio Corp., 475 U.S. 574, 587 (1986) (citation omitted).

IV. DISCUSSION

Plaintiff's Complaint contains seven counts: (1) negligence, (2) strict liability under Restatement (Second) of Torts § 402A, (3) strict liability under Restatement (Second) of Torts § 402B, (4) breach of express warranty, (5) breach of implied warranty of merchantability, (6) violation of consumer protection law and (7) punitive damages. The first two counts each assert multiple theories of liability. In Count I, plaintiff alleges defendants were negligent in their failure to warn of the dangers of Children's Motrin, and in their testing, marketing and design of the product. In Count II, plaintiff claims defendants are strictly liable for her injuries for their failure to warn of the dangers of Children's Motrin, and design and manufacturing defects in the product.

The Court concludes that granting defendants' motion for summary judgment is appropriate on all claims other than plaintiff's failure-to-warn claims and her claim for punitive damages. As to those claims, the Court denies defendants' motion. The Court addresses each claim in turn.

A. Failure-To-Warn Claims

Plaintiff asserts both negligent and strict liability failure-to-warn claims against all defendants. To succeed on her negligence claim, plaintiff must meet the standard set forth in the Restatement (Second) of Torts § 388. See Overbeck v. Cates, 700 A.2d 970, 972 (Pa. Super. Ct. 1997). That section provides:

> One who supplies directly or through a third person a chattel for another to use is subject to liability to those whom the supplier should expect to use the chattel with the consent of the other or to be endangered by its probable use,

> for physical harm caused by the use of the chattel in the manner for which and by a person for whose use it is supplied, if the supplier
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> (a) knows or has reason to know that the chattel is or is likely to be dangerous for the use for which it is supplied, and
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> (b) has no reason to believe that those for whose use the chattel is supplied will realize its dangerous condition, and
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> (c) fails to exercise reasonable care to inform them of its dangerous condition or of the facts which make it likely to be dangerous.

On her strict liability claim, plaintiff must prove "(1) that the product was defective, (2) that the defect existed when it left the hands of the defendant, and (3) that the defect caused the harm." Schindler v. Sofamor, Inc., 774 A.2d 765, 771 (Pa. Super. Ct. 2001) (citation omitted). "A product is defective due to a failure-to-warn where the product was distributed without sufficient warnings to notify the ultimate user of the dangers inherent in the product." Donoughe v. Lincoln Elec. Co., 936 A.2d 52, 61-62 (Pa. Super. Ct. 2007) (citations omitted).

Defendants raise two arguments in support of their contention that summary judgment is appropriate on the failure-to-warn claims. First, defendants contend that the claims are preempted by federal law. Second, defendants argue that plaintiff cannot prove causation based on the evidence in the record. The Court finds neither argument persuasive.

1. *Preemption*

As a general rule, FDA approval of a drug label does not bar recovery in a state-law failure-to-warn action. Wyeth v. Levine, 129 S. Ct. 1187, 1199 (2009); see also In re Budeprion XL Mktg. & Sales Litig., No. 09-md-2107, 2010 WL 2135625, at *16 (E.D. Pa. May 26, 2010) ("The Supreme Court in Levine broadly and unequivocally held that state law complemented federal law to ensure that drug makers market and sell only safe and effective drugs."). To the contrary, such claims are only preempted where defendant adduces "clear evidence that the FDA

would not have approved the change" that was necessary to comply with state law. Levine, 129 S. Ct. at 1198. This is an "exacting burden" that cannot be met "simply by showing that the FDA approved the label which was in place at the time of the plaintiff's injury." Forst v. Smithkline Beecham Corp., 639 F. Supp. 2d 948, 953-54 (E.D. Wis. 2009).

In this case, defendants assert that plaintiff's failure-to-warn claims are preempted because, in 2006, the FDA declined a citizen petition's request to require manufacturers to include a specific reference to SJS on the warning label. (See Defs.' Mot. for Summ. J., Ex. 7 at 8-9.) In the very same document, however, the FDA agreed with the citizen petition that labeling for drugs like Children's Motrin "should be improved to warn consumers about the risks of severe skin reactions associated with [over-the-counter] ibuprofen products." (Id. at 8.) In other words, the FDA agreed that the ibuprofen label in place prior to 2006 should be strengthened but believed that a "description of symptoms" – including skin reddening, rashes and blisters – of SJS and related ailments would be more helpful to consumers than the names of the diseases themselves. (Id. at 9.)

If plaintiff's only complaint were that the label on the Children's Motrin she ingested in 1996 did not include the words "Stevens-Johnson Syndrome" or the letters "SJS," defendants might have a more compelling preemption argument. But the Complaint goes beyond that to allege, inter alia, that defendants failed to warn that "if a rash, blistering, and/or muscosal reaction developed, that Children's Motrin should be stopped immediately and medical care should be sought." (Compl. ¶ 71.) As noted above, the FDA ultimately agreed in 2006 that a warning about such symptoms should be placed on Children's Motrin, and recommended such a warning at that time.

Defendants have thus failed to adduce "clear evidence" that the FDA would have rejected the stronger labeling plaintiff believes was required. As defendants have not met their "exacting burden," the Court rejects defendants' preemption argument.

2. *Causation*

Defendants further argue that plaintiff cannot maintain her failure-to-warn actions because she cannot show that the lack of a better warning was the proximate cause of her damages. This argument is also unavailing.

Proximate cause is an "essential element" in failure-to-warn cases. Simon v. Wyeth Pharm., Inc., 989 A.2d 356, 368 (Pa. Super. Ct. 2009). To get the question of proximate causation to a jury, plaintiff must introduce evidence to show "some reasonable likelihood that an adequate warning would have prevented the plaintiff from receiving the drug." Demmler v. SmithKline Beecham Corp., 671 A.2d 1151, 1155 (Pa. Super. Ct. 1996). In other words, "the evidence must be such as to support a reasonable inference, rather than a guess, that the existence of an adequate warning might have prevented the injury." Pavlik, 135 F.3d at 881.

Defendants point to the following pieces of evidence that, they assert, demonstrate that there is no genuine issue of material fact as to causation:

> (1) Leland read only the dosing information when initially giving plaintiff the Motrin;
> (2) Plaintiff's doctor recommended taking the Motrin, and Leland followed the doctor's recommendation;
> (3) Leland gave plaintiff an Aleve without reading the warning label;
> (4) Leland's sons still use Children's Motrin; and
> (5) Leland still uses ibuprofen products.

(Defs.' Mot. for Summ. J. at 5-6.) Plaintiff responds that (1) Leland did check the box several times after administering the first dose (and did not call the doctor before administering each dose)

and (2) that plaintiff is entitled to a presumption that a better warning would have been heeded. (Pl.'s Resp to Defs.' Mot. for Summ. J. at 24-26.) Defendants reply, inter alia, that Pennsylvania courts do not apply a heeding presumption in drug warning cases. (Defs.' Reply at 4.)

The Pennsylvania Supreme Court has not ruled on whether a heeding presumption applies in a case such as this. There is authority in the lower state courts and the federal courts to support both sides. Compare Pavlik v. Lane Ltd./Tobacco Exps. Int'l, 135 F.3d 876, 883 (3d Cir. 1998) ("We now predict that Pennsylvania would adopt a rebuttable heeding presumption . . ."), and Steffy v. Home Depot, Inc., No. 06-2227, 2009 WL 904966, at *5 (M.D. Pa. Mar. 31, 2009) ("The plaintiff enjoys the benefit of a rebuttable presumption that an adequate warning would have been heeded if it had been provided."), with Viguers v. Philip Morris USA, Inc., 837 A.2d 534, 537-38 (Pa. Super. Ct. 2003) (holding that heeding presumption did not apply in case alleging inadequate warning on cigarettes). There is no need to resolve this question in the context of the instant motion, however, because regardless of whether a presumption applies, the Court concludes that the question of causation should be left for the jury.

In this case, based on the evidence submitted by the parties, a reasonable jury could conclude that a stronger warning would have been heeded, thus preventing plaintiff's injuries. Although Leland testified that, before administering the first dose of Children's Motrin to plaintiff, she "just double-checked the dosage," (Leland Dep. at 101:3-4), she further testified:

> [L]ater during that week when I was getting just that motherly weird feeling that maybe this Motrin wasn't working good for her, I would study the box and the bottle just to see if there was anything on there that I should look for.

(Id. at 101:8-13.) Leland continued to administer the doses at regular intervals over about three days before plaintiff was admitted to Children's Hospital in Boston. (Id. at 103:6-15.) She was

advised to continue administering the Motrin when she called the pediatrician's office at least twice during that span, but she did not consult with the doctor before administering each dose. (Id. at 103:18-19, 106:7-9.)[4] On these facts, it is not clear whether and to what extent the doctor's advice, the label or other factors influenced Leland's decision to continue giving her daughter Children's Motrin right up until the point she was taken to the hospital on June 1, 1996.

The other pieces of evidence noted by defendants – such as Leland's testimony that she still takes ibuprofen products and her admission that she gave her daughter an Aleve from a stranger without reading the label – may bear on the jury's assessment of whether she would have heeded a stronger warning but are insufficient for the Court to conclude as a matter of law that she would not have done so.

There is thus evidence in the record supporting each side's arguments regarding causation. In such a circumstance, summary judgment is inappropriate. Accordingly, the Court denies defendants' motion for summary judgment on plaintiff's failure-to-warn claims.

B. Other Negligence Claims

Although plaintiff's Complaint only contains one "count" related to negligence (Count I), the count includes within it four distinct theories of recovery: (1) negligent failure to warn, (2) negligent failure to test, (3) negligent marketing and (4) negligent design defect. Defendants are

[4] Defendants did not argue in their motion that the learned intermediary doctrine should foreclose liability in this case. As applied to prescription drugs, that doctrine provides that a manufacturer's duty to warn is limited to providing adequate warnings for the prescribing physician. See Rosci v. AcroMed, Inc., 669 A.2d 959, 969 (Pa. Super. Ct. 1995). The Court notes that the rationale underlying the doctrine – that the prescribing physician is always the party making the "final judgment" as to whether a patient should take a certain drug – is inapplicable to over-the-counter medicines, such as the Children's Motrin involved in this case, which are available to the public without prescriptions. See Leibowitz v. Ortho Pharm. Corp., 307 A.2d. 449, 457-58 (Pa. Super. Ct. 1973).

not entitled to summary judgment on the failure-to-warn claim, see Section IV.A, supra, but are entitled to summary judgment on the other three negligence claims.

1. *Negligent Failure to Test*

First, Pennsylvania does not recognize a tort for negligent failure to test. Viguers, 837 A.2d at 541. ("[T]he claim for 'negligent failure to test' is not a viable cause of action recognized by our courts, and we have found no 'duty to test' that would be the basis of such a claim."). Courts have held that such a claim is "logically subsumed within plaintiff's defective design or defective manufacture claims." Shires v. Celotex Corp., No. 85-7141, 1988 WL 1001970, at *2 (E.D. Pa. Mar. 30, 1988). Thus, the Court grants defendants' motion for summary judgment on this claim.

2. *Negligent Marketing*

Second, Pennsylvania does not recognize a tort for negligent marketing. See Owens v. Wyeth, No. 185 EDA 2009, 2010 WL 2965014, at *6 (Pa. Super. Ct. July 26, 2010). A plaintiff can bring a claim that the manner in which a drug is promoted negated otherwise-adequate warnings. See Baldino v. Castagna, 478 A.2d 807, 810 (Pa. 1984). The allegation in this case, however, is not that an otherwise-adequate warning was nullified but that the warning itself was insufficient. Thus, the Court grants the motion for summary judgment as to this claim.

3. *Negligent Defective Design*

Third, regarding the negligent defective design claim, as in any negligence action, the plaintiff "must show that the defendant had a duty to conform to a certain standard of conduct, that the defendant breached that duty, that such breach caused the injury in question, and actual loss or damage." Berrier v. Simplicity Mfg., Inc., 563 F.3d 38, 61 (3d Cir. 2009) (quoting

Phillips v. Cricket Lighters, 841 A.2d 1000, 1008 (Pa. 2003)).

The existence of a duty is a question of law for the court. Id. Resolving whether such a duty is owed is a "policy decision" that requires the Court to balance five factors. Hoffman v. Paper Converting Machine Co., 694 F. Supp. 2d 359, 368 (E.D. Pa. 2010). Those factors are: "(1) the relationship between the parties; (2) the social utility of the actor's conduct; (3) the nature of the risk imposed and foreseeability of the harm incurred; (4) the consequences of imposing a duty upon the actor; and (5) the overall public interest in the proposed solution." Althaus ex rel. Althaus v. Cohen, 756 A.2d 1166, 1169 (Pa. 2000). "[A] duty will be found to exist where the balance of these factors weighs in favor of placing such a burden on a defendant." Phillips, 841 A.2d at 1008-09.

Balancing the five factors, the Court concludes that defendants did not have a duty to plaintiff to develop a safer Children's Motrin product. On the first factor, the relationship between the parties counsels in favor of finding a duty, as plaintiff was an intended user of the product. On the other hand, the second factor weighs in favor of defendants as the social utility of ibuprofen – the active ingredient in Children's Motrin – cannot be doubted. Over the last two decades, Americans have annually purchased more than 6 billion doses of the drug. (Defs.' Mot. for Summ. J., Temple Decl. ¶ 4.)

Third, the risk plaintiff asserts was imposed – development of SJS – is serious, indeed, but extremely rare. According to the FDA, there are an estimated one to six cases of SJS diagnosed per million people per year from all causes. (Pl.'s Resp. to Defs.' Mot. for Summ. J., Ex. F at 3.) It is unclear what percentage of those cases are caused by ibuprofen. Even if SJS is somewhat more prevalent than the FDA asserts, (see id.), diagnosis of the disease is still

anomalous. Because of the disease's extreme rarity, the third factor favors defendants.

The fourth and fifth factors strongly favor defendants and are, in the Court's view, dispositive. The consequences of imposing on defendants a duty to develop a safer ibuprofen product, the fourth factor, would be severe because there exist no other FDA-approved forms of ibuprofen. (Temple Decl. ¶ 16.) In at least the short term, a popular pain reliever would have to be removed from pharmacies. This would run counter to the fifth factor: the public's interest in continued use of a product it values for its palliative abilities.

In sum, defendants do not have a duty to plaintiff to manufacture a safer ibuprofen product. The Court grants the motion for summary judgment on plaintiff's negligent design defect claim.

C. Other Strict Liability Claims

Though all subsumed with one count (Count II), plaintiff's complaint raises three claims of strict liability under the Restatement (Second) of Torts § 402A: (1) failure to warn, (2) manufacturing defect and (3) design defect. Defendants are not entitled to summary judgment on the failure-to-warn claim, for the reasons stated in Section IV.A, supra. However, they are entitled to summary judgment on the other two strict liability claims.

As noted above, in all products liability cases, the plaintiff must prove "(1) that the product was defective, (2) that the defect existed when it left the hands of the defendant, and (3) that the defect caused the harm." Schindler, 774 A.2d at 771 (citation omitted). Plaintiff can prove a manufacturing defect by demonstrating a "breakdown" in the product or one of its components and a design defect by showing that the design of the product itself renders it "unreasonably dangerous." Id.

1. *Manufacturing Defect*

On the manufacturing defect claim, plaintiff has presented no evidence that the Children's Motrin plaintiff ingested deviated from defendants' design specifications or was otherwise improperly manufactured. In such a circumstance, granting a motion for summary judgment is appropriate. See, e.g., Zombeck v. Amada Am., Inc., No. 06-953, 2009 WL 1423347, at *2 (W.D. Pa. Mar. 20, 2009). Therefore, the Court grants defendants' motion for summary judgment as to this claim.

2. *Design Defect*

On the design defect claim, Pennsylvania courts apply seven suggested factors in determining whether a product is unreasonably dangerous:

> (1) The usefulness and desirability of the product – its utility to the user and to the public as a whole;
> (2) The safety aspects of the product – the likelihood that it will cause injury, and the probable seriousness of the injury;
> (3) The availability of a substitute product which would meet the same need and not be as unsafe;
> (4) The manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility;
> (5) The user's ability to avoid danger by the exercise of care in the use of the product;
> (6) The user's anticipated awareness of the dangers inherent in the product and their avoidability, because of general public knowledge of the obvious condition of the product, or of the existence of suitable warnings or instruction; and
> (7) The feasibility, on the part of the manufacturer, of spreading the loss [by] setting [a higher] price of the product or carrying liability insurance.

Surace v. Caterpillar, Inc., 111 F.3d 1039, 1046 (3d Cir. 1997) (citations omitted). These factors overlap substantially with the five factors used to assess whether to apply a duty in a negligence

case. See Section IV.B, supra. After analyzing these factors, the Court concludes that plaintiff cannot succeed on her strict liability defective design claim as a matter of law.

The first, third and fourth factors all strongly weigh in defendants' favor. Ibuprofen is a widely used product, and plaintiff has produced no evidence that it can be made safer (other than through the additions of warnings). There exists no FDA-approved alternative form of ibuprofen, meaning there is no available alternative design of the drug for defendants to adopt.

The second factor also weighs in defendant's favor, albeit to a lesser extent. As noted above, while SJS is a serious disease, the chances of contracting it from any source are minuscule. Thus, the Court concludes that the "safety aspects" of Children's Motrin do not support the claim that the product was defectively designed.

The fifth through seventh factors have little bearing on the Court's analysis. Regarding the fifth and sixth factors, plaintiff has presented evidence that the warning on Children's Motrin was inadequate and that better warnings might have caused her to stop using the medicine. If anything, however, this evidence tends to undercut the assertion that a user of Children's Motrin, if given proper warnings, would be unaware of the dangers associated with the product and unable to exercise due care to avoid or mitigate those dangers.

Finally, there is no evidence in the record about the feasibility of increasing the costs of Children's Motrin. There is also no evidence regarding the cost of additional liability insurance defendants would have to carry as a result of a finding that ibuprofen is unreasonably dangerous.

After balancing the seven factors, the Court concludes that plaintiff has failed to create a

genuine issue of material fact as to whether Children's Motrin was defectively designed.[5] Accordingly, the Court grants defendants' motion for summary judgment as to the strict liability defective design claim.

D. Misrepresentation

In Count III, plaintiff raises a claim against defendants for misrepresentation under § 402B of the Restatement (Second) of Torts. That section reads:

> One engaged in the business of selling chattels who, by advertising, labels, or otherwise, makes to the public a misrepresentation of a material fact concerning the character or quality of a chattel sold by him is subject to liability for physical harm to a consumer of the chattel caused by justifiable reliance upon the misrepresentation, even though
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> (a) it is not made fraudulently or negligently, and
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> (b) the consumer has not bought the chattel from or entered into any contractual relation with the seller.

Pennsylvania has adopted this section of the Restatement. See Klages v. Gen. Ordnance Equip. Corp., 367 A.2d 304, 310 (Pa. Super. Ct. 1976). The rule applies only to misrepresentations of "material facts" and only where there has been "justifiable reliance" on the misrepresentation. Restatement (Second) of Torts § 402B, cmts. g, j.

Plaintiff in this case alleges that the statement on the Children's Motrin label that consumers should "[s]ee box for complete information" constituted a misrepresentation because the box did not, in fact, contain "complete information" about the risks of taking the drug. Plaintiff fails, however, to identify any specific misrepresentation on the labels about the quality

[5] The Court also notes that a finding that an FDA-approved drug was unreasonably dangerous could raise preemption concerns as well. The Court need not examine the preemption issue, however, because it has already concluded as a matter of law that Children's Motrin is not unreasonably dangerous.

of the product itself. Moreover, even if the general statement that the box contained "complete information" amounted to a misrepresentation, plaintiff's claim would still fail because she has not presented any evidence that she, her mother or any other party relied on that representation when purchasing or consuming the product. Thus, the Court grants defendants' motion for summary judgment on plaintiff's misrepresentation claim.

E. Warranty Claims

Plaintiff brings two claims for breach of warranty: (1) breach of express warranty (Count IV) and (2) breach of the implied warranty of merchantability (Count V). Neither claim can survive the motion for summary judgment.

1. *Express Warranty*

In Pennsylvania, "[a]ny description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description." 13 Pa. Cons. St. § 2313(a)(2). To satisfy the "basis of the bargain" requirement, a plaintiff must prove that she "read, heard, saw or knew"about the particular statement she alleges constituted a warranty. Parkinson v. Guidant Corp., 315 F. Supp. 2d 741, 752 (W.D. Pa. 2004).

In this case, plaintiff does not point to any specific description of Children's Motrin that formed the "basis of the bargain" between plaintiff and defendants, nor does she cite to any evidence that she "read, heard, saw or knew" of such a statement when she purchased the product. Thus, the Court grants defendants' motion for summary judgment on the express warranty claim.

2. *Implied Warranty of Merchantability*

As for the implied warranty of merchantability, a merchant is generally required to ensure that its products are "fit for the ordinary purposes for which such goods are used." 13 Pa. Cons. St. § 2314(b)(3). A seller is not, however, required to guarantee against every possible harm that results from the use of its products. See Morris v. Pathmark Corp., 592 A.2d 331, 334 (Pa. Super. Ct. 1991) ("[T]he law in Pennsylvania is well settled that a seller cannot be liable for breach of an implied warranty merely because of a harmful effect due to an individual idiosyncrasy on the part of the buyer."); see also Whitson v. Safeskin Corp., 313 F. Supp. 2d 473, 480 (M.D. Pa. 2004).

As noted above, SJS is an extremely rare disease. It is difficult to label an illness that is diagnosed six or fewer times per million people per year anything other than idiosyncratic, even if defendants foresaw or should have foreseen that it was a possible reaction to their product. Plaintiff may have been entitled to a better warning about the dangers of ibuprofen – an issue that, as the Court has already ruled, should be reserved for the jury – but "[i]t can't be argued seriously that McNeil implicitly warranted that Children's Motrin will not cause SJS. . . . That would imply that the company had a duty to guarantee against every conceivable adverse consequence of taking the drug, however remote, esoteric, or even conjectural; and that is not the law." Robinson v. McNeil Consumer Healthcare, 615 F.3d 861, 873 (7th Cir. 2010).

Thus, the Court grants the motion for summary judgment on the breach of the implied warranty of merchantability claim.

F. Consumer Protection Violation

Plaintiff raises a claim for violation of the Pennsylvania Unfair Trade Practices and Consumer Protection Law ("UTPCPL"), 73 Pa. Cons. St. § 201-1 et seq.[6] The Court concludes that there is not a "sufficient nexus" between the activity at issue in this case and Pennsylvania and accordingly grants defendants' motion for summary judgment on this claim.

This Court has previously held that "the UTPCPL provides a remedy only to Pennsylvania residents." Baker v. Family Credit Counseling Corp., 440 F. Supp. 2d 392, 413 (E.D. Pa. 2006). At the very least, a plaintiff must allege a "sufficient nexus" with Pennsylvania. See Haggart v. Endogastric Solutions, Inc., No. 10-346, 2011 WL 466684, at * 7 (W.D. Pa. Feb. 4, 2011) (holding a claim cognizable under the UTPCPL where plaintiff's surgery with an allegedly defective product was performed by a Pennsylvania surgeon in a Pennsylvania hospital).

Plaintiff in this case is not a Pennsylvania resident – she lived in Maine at the time of the injury and now resides in Louisiana. The central events of the case – plaintiff's ingestion of Children's Motrin and her subsequent hospitalization and diagnosis – occurred in Maine and Massachusetts. That some of the defendants maintain principal places of businesses in Pennsylvania is simply too attenuated a connection to support a UTPCPL claim.

Plaintiff argues that defendants stipulated to the UTPCPL's applicability – or at least waived any defense to the contrary – when they agreed with plaintiff's assertion that

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[6] The Complaint actually alleges generically a "violation of consumer protection law." (Compl. at 17.) The parties agreed that Pennsylvania law should be applied to the claim. Thus, the Court analyzes the claim under the UTPCPL.

Pennsylvania law should govern the claim. This is simply incorrect. Defendants wrote in their memorandum on choice-of-law issues that "[p]laintiff has indicated a preference that Pennsylvania law govern and Defendants do not disagree." (Defs.' Resp. to Pl.'s Choice-of-Law Mem. at 2 n.1.) Defendants never conceded that plaintiff had pleaded or could prove a valid UTPCPL claim.

As defendants have not stipulated to the applicability of the UTPCPL, and plaintiff has not alleged a "sufficient nexus" between the events in this case and the Commonwealth of Pennsylvania, the Court grants defendants' motion for summary judgment on the UTPCPL claim.

G. Claim for Punitive Damages

Finally, defendants seek summary judgment on plaintiff's claim for punitive damages (Count VII).[7] The Court concludes, however, that there remains a genuine issue of material fact as to this claim. Thus, the motion for summary judgment is denied as to the punitive damages claim.

The Court determined in its July 30, 2010 Memorandum on choice-of-law issues that Maine law applied to the claim for punitive damages. Under Maine law, punitive damages may be awarded only upon a showing that the defendant acted with express or implied "malice." Tuttle v. Raymond, 494 A.2d 1353, 1361 (Me. 1985). Express malice exists where "defendant's

[7] Although stated as a separate count, plaintiff's claim for punitive damages is not a separate cause of action because it is dependent on plaintiff's ability to recover compensatory damages. See Jolovitz v. Alfa Romeo Distribs. of N. Am., 760 A.2d 625, 629 (Me. 2000) ("[A] claim for punitive damages will not lie unless the plaintiff receives compensatory or actual damages based on the defendant's tortious conduct.").

tortious conduct is motivated by ill will toward the plaintiff." Id. Implied malice exists where "deliberate conduct by the defendant, although motivated by something other than ill will toward any particular party, is so outrageous that malice toward a person injured as a result of that conduct can be implied." Id. A defendant's "mere reckless disregard of the circumstances" does not constitute implied malice. Id. Plaintiff must prove that defendant acted with malice by "clear and convincing evidence." Id. at 1363.

Viewing the evidence in the light most favorable to plaintiff, a reasonable jury could conclude that plaintiff has met her burden of proving punitive damages. Although plaintiff has provided no evidence of express malice, she has presented evidence from which a jury could infer implied malice – concealment of data from the FDA.

Plaintiff has presented evidence that defendants concealed from the FDA two cases of SJS found in patients during a massive study it commissioned on the safety of OTC ibuprofen use. Defendants acknowledged receiving reports of the two cases of SJS. (Pl.'s Resp. to Defs.' Mot. for Summ. J., Ex. N at 4846-47.) Yet a subsequent Clinical Study Report issued by McNeil describing the results of the study did not mention these two reports. (See Temple Decl. ¶ 21-22; Pl.'s Resp. to Defs.' Mot. for Summ. J., Ex. O.)

Defendants assert that the FDA was, in fact, apprised of the two reports. (Temple Decl. ¶ 21.) That may be true. However, a reasonable jury viewing the evidence in the light most favorable to plaintiff could conclude otherwise. If the jury does conclude that defendants deliberately concealed information from the FDA – both to win FDA approval of OTC Children's Motrin and to avoid the need to warn of SJS or its symptoms – the jury could well

find that plaintiff demonstrated, by clear and convincing evidence, the sort of outrageous conduct that would justify the imposition of punitive damages.[8]

Defendants argue that, even if plaintiff can prove that defendants concealed pertinent information from the FDA, plaintiff cannot recover punitive damages based on such concealment because such an award would be preempted under Buckman v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001). In Buckman, the Supreme Court held that a state-law claim for fraud on the FDA was preempted by federal law. Id. at 353. The Court noted, inter alia, that policing the relationship between a party and a federal agency is "hardly a field which the States have traditionally occupied." Id. at 347 (citation and internal quotation marks omitted). Thus, the Court reasoned, there was no need to apply the traditional presumption against preemption. Id. at 348.

By contrast, in this case, Maine's provision for the award of punitive damages in appropriate cases is not an "attempt to police fraud against the FDA." Desiano v. Warner-Lambert & Co., 467 F.3d 85, 94 (2d Cir. 2006). Rather, it is part of the state's traditional role of regulating "matters of health and safety." Id. (citation omitted). Evidence that defendants concealed material information from the FDA is not being used to establish liability in this case but to demonstrate that the offending failure-to-warn conduct was not merely sufficient to

[8] Plaintiff further asserts that summary judgment on the question of punitive damages is inappropriate because defendants (1) knew of the risks of ibuprofen more than a decade before plaintiff's injury but failed to provide a proper warning and (2) failed to take appropriate action upon learning that an individual who had taken ibuprofen developed liver disease. While these arguments are less strong indicators of outrageous conduct, when considered in conjunction with the alleged withholding of information from the FDA, they could contribute to an overall finding of outrageous behavior.

establish strict liability or negligence but was truly outrageous.

Plaintiff has presented sufficient evidence to create a genuine issue of material fact as to whether defendants acted with implied malice in failing to warn of the dangers of Children's Motrin. Thus, the Court denies defendants' motion for summary judgment as it relates to plaintiff's claim for punitive damages.

V. CONCLUSION

For the foregoing reasons, the Court denies defendants' motion for summary judgment as to plaintiff's failure-to-warn claims and claim for punitive damages, and grants the motion in all other respects. An appropriate order follows.